REMARKS/ARGUMENTS

Favorable reconsideration of this application is requested in view of the amendments above and the remarks which follow.

DISPOSITION OF CLAIMS

Claims 59, 61-63, 69-72, and 76-81 are pending in this application. Claims 53, 55, 58, 60, 64-68, 73-75 have been canceled. Claims 76-81 are new. Claim 76 was derived from previous claims 64-68 and is supported by the specification as originally filed (see, for example, page 7, lines 5-9 and 24-31 and page 20, line 30 to page 21, line 14). Claim 77 was derived from previous claim 58. Claim 78 was derived from previous claim 74. Claim 79 is supported by Example 1 in the specification as originally filed. Claim 80 was derived from previous claim 73. Claim 81 was derived from previous claim 60. The claims have been amended as set forth above such that the invention is directed to a sustained release oral dosage form only.

REJECTIONS UNDER 35 U.S.C. §103

In the Office Action dated February 15, 2007, claims 53, 55, 58-75 were rejected under 35 USC 103 as being unpatentable over Rudnic et al. (U.S. Patent No. 5952004) in view of Eckenhoff et al. (U.S. Patent No. 4692326), and further in view of Al Razzak et al. (U.S. Patent No. 5559158). Claims 53, 55, 58, 60, 64-68, 73-75 have been canceled. Reconsideration of the rejection of claims 59, 61-63, and 69-72 is respectfully requested.

Claims 59, 61-63, and 69-72 ultimately depend from claim 76. Therefore, if it can be shown that claim 76 is patentable over the cited references, then claims 59, 61-63, and 69-72 would also be patentable over the cited references.

Claim 76 recites a sustained release oral dosage form ***consisting*** of a capsule containing a liquid antiviral drug composition, an exit orifice extending from an external surface of the capsule to an environment of use, an expandable layer located within the capsule and remove from the exit orifice or contacting the external surface of the capsule, a semipermeable layer surrounding the external surface of the capsule and an optional barrier layer located between the capsule and the expandable layer or between the liquid antiviral drug composition and the expandable layer. The liquid antiviral drug composition ***consists*** of an antiviral drug solubilized

in a liquid non-ionic surfactant, wherein the antiviral drug is present in the composition in an amount of about 5 wt% to about 60 wt%, the liquid non-ionic surfactant is present in the composition in an amount of about 20 wt% to about 95 wt%, and the liquid antiviral drug composition is substantially free of in-situ aggregation effect of the antiviral drug.

In Table 3, Rudnic et al disclose a waterless microemulsion system including Tween 80, Arlacel 186, and Oleyl alcohol for transport of peptides across Caco-2 cells. Solubilizing of a drug in this waterless microemulsion system is not disclosed. In the other examples, Rudnic et al disclose formulations including an aqueous phase, either in the form of water, distilled water, or Hank's buffer, along with a surfactant and an oily phase. Rudnic et al do not disclose a liquid antiviral drug composition consisting of an antiviral drug solubilized in a liquid non-ionic surfactant, as recited in claim 76. Hydration of an antiviral drug inside an oral dosage form can lead to aggregation of the antiviral drug. Drug aggregation could lead to an erratic release profile. The liquid antiviral drug composition recited in claim 76 is a non-aqueous, isotropic, homogeneous drug solution and is less susceptible to aggregation of the antiviral drug. Further, as demonstrated in Example 1 of the instant application, a high amount of antiviral drug can be solubilized in a liquid non-ionic surfactant alone. For example, in Example 1 in the instant application, the liquid antiviral drug composition contained 50 wt% of nelfinavir. Rudnic et al. do not disclose formulations containing more than 5 wt% of a drug.

Eckenhoff et al and Al-Razzak et al fail to overcome the deficiency in Rudnic et al. It is respectfully noted that Al-Razzak et al teach a ***solid*** pharmaceutical composition, whereas the claimed invention is directed to a sustained release oral dosage form including a ***liquid*** antiviral drug composition. In Al-Razzak et al, a mixture of an organic solvent, a HIV protease inhibitor, and an acid is adsorbed onto a pharmaceutically acceptable adsorbent, thereby forming a solid pharmaceutical composition. It is this solid pharmaceutical composition that is disposed in a capsule. Al-Razzak et al, whether considered alone or in combination with Rudnic et al, clearly do not teach a liquid antiviral drug composition consisting of an antiviral drug solubilized in a liquid non-ionic surfactant contained in a capsule, as recited in claim 76. Along the same lines, disposing the solid pharmaceutical composition taught by Al-Razzak et al and/or the emulsions taught by Rudnic et al in the dispenser of Eckenhoff et al would not render claim 76 obvious.

From the foregoing, claim 76 is not obvious over Rudnic et al in view of Al-Razzak et al and further in view of Eckenhoff et al. Also, claims 59, 61-63, and 69-72 are not obvious over

these cited references by virtue of their dependence from claim 76. Withdrawal of the rejection of claims 59, 61-63, and 69-72 is respectfully requested.

CONCLUSION

Applicant believes that this paper is fully responsive to the Office Action dated February 15, 2007. Please apply any charges not covered or credits in connection with this filing to Deposit Account No. 50-3202 (ref. ARC2644R1).

Respectfully submitted,

Date: May 15, 2007

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